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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,806	03/31/2004	Constantin Cope	8627/487 (PA-5391RFB)	7536
27879 7590 05/30/2007 INDIANAPOLIS OFFICE 27879 BRINKS HOFER GILSON & LIONE ONE INDIANA SQUARE, SUITE 1600 INDIANAPOLIS, IN 46204-2033			EXAMINER BOUCHELLE, LAURA A	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 05/30/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/813,806	<b>Applicant(s)</b> COPE ET AL.	
	<b>Examiner</b> Laura A. Bouchelle	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7-14 and 16-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-14 and 16-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 2, 7-10, 14, 16-18, 21-24, 29, 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Osypka et al (US 2003/0216771). Osypka discloses a vascular introducer assembly with a hemostatic seal comprising a needle 18, a needle hub 20, a needle hub attachment assembly 22, and a hemostatic segment comprising a guidewire inserter 28. The distal end of the hemostatic segment tapers to an endhole having a diameter substantially the same as the guidewire 86. See Fig. 5. The device comprises two elastomeric valves 58, 80. The needle hub and the hub attachment assembly are connected through a leak free threaded engagement.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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4. Claims 3,4, 12, 19, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka in view of Raulerson et al (US 6551281). Claims 3, 4, 19, 32 differ from Osypka in calling for the hemostatic segment to include a guidewire holder that is preloaded with a guidewire. Claim 12 calls for the holder to fasten the guidewire in a loop. Raulerson teaches a guidewire advancer comprising a guidewire holder 24 that is preloaded with a guidewire 21 fastened in a loop so that the guidewire can be easily manipulated by the user and remain sterile while it is inserted into the patient through the introducer device 30. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the device of Osypka a preloaded guidewire holder as taught by Raulerson so that the guidewire can be easily manipulated by the user and remain sterile while it is inserted into the patient through the introducer device.

5. Claims 11, 20, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka in view of Padilla et al (US 5984895). Claims 11, 20, 31 differ from Osypka in calling for the needle hub attachment assembly to be transparent. Padilla teaches a vascular blood flashback containment device comprising a hub attachment assembly 38 that is transparent to allow for visualization of blood contained in that segment (Col. 6, lines 12-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Osypka to include a transparent portion as taught by Padilla to allow for visualization of blood contained in the hub attachment area.

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6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Osypka. Claim 13 differs from Osypka in calling for a luer lock connection. At the time the invention was made, it would have been an obvious matter of design choice to use a luer lock connection. Applicant has not disclosed that having a luer lock serves any advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill would expect Osypka and applicant's invention to perform equally well with either a threaded connection or a luer lock because both are well known methods of forming fluid tight seals. Therefore, it would have been prima facie obvious to modify Osypka to obtain the invention as specified in claim 13 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

#### ***Response to Arguments***

7. Applicant's arguments, see pages 8, 9, filed 3/6/07, with respect to the rejection(s) of claim(s) 1,2,5,7,8,13-16,30 under Raulerson (US 5045065) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Osypka et al (US 2003/0216771).

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**NICHOLAS D. LUCCHESI**  
**SUPERVISORY PATENT EXAMINER**  
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Laura A Bouchelle  
Examiner  
Art Unit 3763

